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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,732	12/21/2001	James A. Brady	9386.17711-A	4455

7590 05/03/2004

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,732

Applicant(s)

BRADY ET AL.

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 1-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 47-80 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/29/03, 6/30/03, 7/28/03, 4/18/03</u> | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 47-80 in the response filed February 17, 2004 is acknowledged.

Specification

The disclosure is objected to because of the following informalities: Applicants continuing data statement on page 1 is not up to date. Specifically, 09/294,224 is no longer copending, and has been issued as a patent. Furthermore, each application must be recited as a continuation, division or continuation in part, as appropriate from the preceding application. Reference to "claiming benefit under 35 U.S.C. 120 is not appropriate. (Line 16). Furthermore, is 09/832,159 a CIP of 09/829,252? The first lines of the specification are unclear on this.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. Claims 47-80 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 47-80 are directed to blood processing methods comprising the steps of

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conveying the blood drawn from an individual to an extracorporeal apparatus, operating the extracorporeal apparatus to conduct separation of the blood into plasma and at least one cellular blood component, and removing cytokines or other species of proinflammatory or anti-inflammatory stimulators or mediators from either plasma, or the at least one cellular blood component, or both.

While those of skill in the art would be able to recognize a cytokine, the same is not true for “other species of pro-inflammatory or anti-inflammatory stimulators or mediators.”

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, “other species of pro-inflammatory or anti-inflammatory stimulators or mediators” alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 “Written Description” Requirement, Federal Register,

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Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

2. Claims 61, 69 and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "having a surface modified to minimize activation of blood complement." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, what level of activation is permitted to still qualify as minimal? Likewise at what level does the activation rise to the level of no longer minimal? Without a clear definition as to the terms "surface modified to minimize activation of blood complement" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

3. Claims 63, 71 and 80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "close to those of θ -solvents." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, what property is being measured, and at what point does the property differ enough to no longer be considered as "close?" Without a clear definition as to the terms "close to those of θ -solvents" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 47-80 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Onodera et al.

Claims 47-80 are directed to blood processing methods comprising the steps of conveying the blood drawn from an individual to an extracorporeal apparatus, operating the extracorporeal apparatus to conduct separation of the blood into plasma and at least one cellular blood component, and removing cytokines or other species of proinflammatory or anti-inflammatory stimulators or mediators from either plasma, or the at least one cellular blood component, or both.

Onodera et al (US Patent Number 5,407,581) disclose of blood processing methods comprising conveying blood drawn from an individual to an extracorporeal apparatus. (See column 33). Onodera et al further disclose of separating whole blood into plasma and a blood cell product. (See columns 3-4). Onodera et al further disclose of removing cytokines. (See column 49). Onodera et al further disclose of the polymeric material 2-hydroxyethyl methacrylate and divinylbenzene. (See columns 16 and 43).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
April 29, 2004